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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,683	07/19/2002	James S. Nowick	UCIVN-001US	3685

7590 11/26/2004

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,683

Applicant(s)

NOWICK ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
4a) Of the above claim(s) 2-9 and 12-31 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 10 and 11 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' election of Group 1 (claims 1, 10, 11) with traverse is acknowledged, as is the elected specie (the compound recited in claim 10). Claims 1, 10, 11 are examined in this Office action; claims 2-9, 12- 31 are withdrawn from consideration.



An abstract is required, and does not appear to have been submitted.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10, 11 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have determined (fig 7) the NMR chemical shifts of the *alpha*-protons of Phe and Val in "tripeptide A" as a function of concentration (of "tripeptide A") in CDCl₃. Applicants have also asserted (page 12, line 1) that in 10% CD₃OD/CDCl₃,

dimerization of tripeptide A occurs with a K_{dim} of 900 M^{-1} . Applicants have also proposed various structural models. Such models may, at some point in the future, prove to be relevant to the actual structures present in solution. But as matters currently stand, all that applicants have provided evidence for is the proposition that tripeptide A can dimerize in chloroform, or in chloroform containing 10% methanol.

Applicants have asserted (page 5, line 4+) that if the compounds of claim 1 are incorporated into peptides, such proteins will dimerize by means of beta-sheet interactions. Also asserted (page 5, line 12+) is that if one of the claimed compounds is "incorporated into a drug or agent", it will block the beta-sheet dimerization of proteins. First, applicants have not actually shown that there exists two proteins which dimerize in the absence of the claimed compounds, but will not dimerize in the presence of any of the claimed compounds. Nor have applicants even shown that any of the claimed compounds can dimerize in aqueous solution. Further, there is no guidance as to which peptides one should incorporate the claimed compounds into, or which proteins they might possibly inhibit the dimerization of. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the

invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. Thus, there are no working examples which show one how to inhibit dimerization of proteins, and no guidance as to which peptides one should incorporate the claimed compounds into, or which proteins they will inhibit the dimerization of. Nor is there any guidance provided by the prior art which can be applied to the claimed compounds. In addition, one cannot predict, merely by viewing a structure, which compounds will inhibit dimerization of a given pair of proteins. In accordance with the foregoing, "undue experimentation" would be required to practice the claimed invention.



Claim 1 is objected to because of a grammatical error. In line 1 of the claim, the word "have" is present. However, this is grammatically incorrect in this situation.



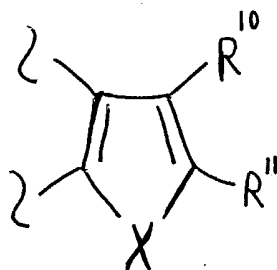
Claims 1, 10, 11 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 is drawn to a "composition". A composition, however, must contain at least two compounds. A "composition" that consists of just one compound is not a composition, rather, it is just a compound *per se*. It is suggested that either of the following be done:

- (a) delete the word "composition" from line 1 of claim 1, and replace it with - - compound - - , or
 - (b) retain the word "composition" in claim 1, but specify the nature of a second compound that is present, or a composition that is present in addition to the compound (for which the structure is provided).
- The definition of "W", in conjunction with the indicated structure, generates an ambiguity in claim 1. The claim recites the following:

"W is hydrogen or fluorine or **the** NHCOCOZ group shown".

It is unclear what exactly is meant by "**the** NHCOCOZ group shown". One interpretation is that when "W" is other than hydrogen or fluorine, then "W" must be NHCOCOZ, and at the same time the adjacent position on the ring must be hydrogen. Another interpretation is that when "W" is other than hydrogen or fluorine, then "W" must be NHCOCOZ, and at the same time the adjacent position on the ring can also be NHCOCOZ. Which of these is intended? One option for enhancing clarity would be to define two new variables, e.g., R^{10} and R^{11} , and to provide the following structure (only a partial structure is shown here for simplicity):



These two variables could then be defined as follows:

R^{10} is hydrogen or fluorine or NH-CO-CO-Z;

R^{11} is hydrogen or NH-CO-CO-Z;

with the proviso that one of R^{10} and R^{11} is NH-CO-CO-Z.

- Claim 1 recites that variable "X" can represent $CR^4=N$. However, this requires the carbon atom bearing R^4 to be pentavalent. Similarly, claim 1 recites that variable "X" can represent $CR^4=R^5$. Again, this requires the carbon atom bearing R^4 to be pentavalent.
- Claim 1 recites that " R^3 is aryl... which may be straight or branched...[or] chiral". Applicants are requested to provide an example of a compound in which R^3 is aryl, and for which, at the same time, R^3 is either "straight" or "chiral".
- In claim 10, the phrase "tripeptide compound" lacks antecedent basis in claim 1.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800